

JUN - 6 1997

K 971701

**510(k) SUMMARY**

Continu-Flo® Solution Sets with Modified Check Valve

**Submitted by:**

Mary Ellen Snyder  
Baxter Healthcare Corporation  
I.V. Systems Division  
Rte. 120 and Wilson Road  
Round Lake, IL 60073

**Date Prepared:**

May 7, 1997

**Proposed Device:**

Continu-Flo® Solution Sets with Modified Check Valve

**Predicate Devices:**

Continu-Flo® Solution Sets with Check Valve

**Proposed Device Description:**

The proposed Continu-Flo® sets contain a check valve which prevents backflow of solution from the secondary medication container into the primary container during administration of secondary medication. The current check valve is a disc valve and is positioned in the set tubing between the drip chamber and Y-injection site. The new check valve is a duck bill valve and is positioned inside the Y-injection site housing of the set.

There is one material in the proposed check valve design which is new to Baxter devices. The valve itself will be formulated from a new polyisoprene material. The materials used on the proposed check valve cap and housing, are the same as those in use on the current check valve body and Y-injection site housing on Continu-Flo® solution sets. All other materials in the solution sets remain unchanged.

**Statement of Intended Use:**

Continu-Flo® solution sets with the proposed check valve have the same intended use as the currently marketed sets. The intended use of these sets is the administration of fluids from a container to the patient's vascular system. Continu-Flo® sets contain a check valve which prevents backflow of solution from the secondary medication container into the primary container during the administration of secondary medication.

MAY 07 1997

45

## **Summary of Technological Characteristics of New Device to Predicate Devices**

The proposed solution sets are identical to currently marketed Continu-Flo® Solution Sets with Check Valve, previously cleared under K881052, except for the design and location change of the check valve component. The current check valve is a disc valve and is positioned in the set tubing between the drip chamber and Y-injection site. The proposed check valve is a duck bill valve and is positioned inside the Y-injection site housing of the set. All other components of the solution administration sets remain unchanged.

## **Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature**

The biological and chemical reactivity of the new polyisoprene material have been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The material was found to be acceptable for its intended use.

Data regarding the functional performance of the proposed check valve have been generated. A description of the functional testing along with test results is provided. The data indicate that the proposed check valve meets or exceeds all functional requirements and support its suitability for use in Continu-Flo® sets.

MAY 07 1997



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 6 1997

Ms. Mary Ellen Snyder  
Manager, Regulatory Affairs  
Baxter Healthcare Corporation  
Route 120 And Wilson Road  
Round Lake, Illinois 60073

Re: K971701  
Trade Name: Continu-Flo® Solution Sets with Modified  
Check Valve  
Regulatory Class: II  
Product Code: FPA  
Dated: May 07, 1997  
Received: May 08, 1997

Dear Ms. Snyder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

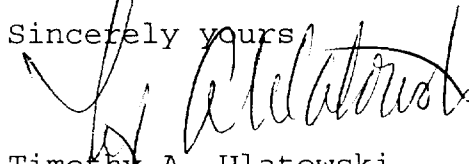
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation

Page 2 - Ms. Snyder

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours

A handwritten signature in dark ink, appearing to read "Timothy A. Ulatowski", is written over the typed name and title.

Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Premarket Notification  
Continu-Flo® Solution Sets  
With Modified Check Valve

510(k) Number: Not Available

Device Name: Continu-Flo® Solution Sets with Modified Check Valve

Indication for Use:

Continu-Flo® solution sets with the proposed check valve have the same intended use as the currently marketed sets. The intended use of these sets is the administration of fluids from a container to the patient's vascular system. Continu-Flo® sets contain a check valve which prevents backflow of solution from the secondary medication container into the primary container during the administration of secondary medication.

(Division Sign-Off) *Patricia Enconite*  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number *K971701*

Prescription Use *✓*  
(Per 21 CFR 801.109)

MAY 07 1997